IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 C.A. No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris

RESPONSE TO TRACK TWO DEFENDANTS' MEMORANDUM IN SUPPORT OF TRACK TWO CLASS ACTION SETTLEMENT

Certain Named Plaintiffs hereby respond to Track Two Defendants' Memorandum in Support of Track Two Class Action Settlement ("Defts Mem.") which seeks to nearly double the number of Subject Drugs included in this case by **adding eighty-five (85) new drugs** to the existing ninety-nine (99) drugs (hereinafter, "Newly-Added Drugs") that were previously stricken from this case by the Court -- **twice** – on motions filed by the Track Two Defendants.

I Introduction

At the outset, two points need to be made to set the record straight as to Track Two Defendants' non-legal assertions about the issue for which *they seek* broad, unprecedented relief from this Court – *ie*., a massive expansion of the scope of the Subject Drugs in the case to give settling defendants a broad release of Class claims for Newly-Added Drugs without paying for them.

First, Certain Named Plaintiffs' objections to the unprecedented expansion of the scope of the release are not "*another effort* to derail the settlement," as Track Two Defendants charge. Defts Mem. at 1. Track Two Defendants disingenuously represent that their submission of a brief was only "prompted by objections to the Track 2 settlement lodged…" during the June 13, 2011 hearing. It is only in their subsequent, pejorative description of the objection as "recycled" (Defts. Mem. at 2), that they indirectly concede that the objection was timely raised back in March 24, 2009, in Certain Named Plaintiffs' brief in opposition to the Track Two settlement. Dkt. No.5971 And, such objection was made without the benefit of what was later brought out at the April 27, 2009 Fairness Hearing – *ie*., that this massive expansion of the scope of the release was prompted by Defendants seeking "as broad a release as possible" [1] without paying for it.[2]

Consequently, it is the meritorious challenge to the scope of the proposed release – which Class Counsel took no position on at the prior Fairness Hearing–

[1] April 27, 2009 Tr. 80:22- (Mr. Berman: "you know, the defendants wanted as broad a release as possible. …And if your Honor thinks that's overbroad, I think you should address that to them.")

[2] As will be shown more fully below, the $125 million Track Two settlement was negotiated for the Subject Drugs only. There has been no representation by any party (or proof to demonstrate) that any of the Newly-Added Drugs were part of the mediation that took place before Professor Green. To the contrary, the record shows the parties utilized Dr. Hartman's figures for the Subject Drugs only.

that has forced the Track Two Defendants off the sidelines to advocate in favor of their settlement with Class Counsel.

Second, what was previously left vague and unclear at the April 27, 2009 Fairness Hearing now is crystal clear: **the settling parties are looking to expand the scope of the Subject Drugs to include Newly-Added Drugs previously stricken by the Court** (including Pharmacia's Trelstar and Aventis' Eligard which the undersigned discussed with the Court on that day). *See* April 27, 2009 Tr. at 72:18-73:23, 74:6-18. Consequently, Class Counsel's prior vehement denial and baseless charge that the undersigned was "wrong" about the contention must be rejected:

> THE COURT: And what about this one I understand the least well, is that drugs were added …
> MR. BERMAN: Well, again, Mr. Haviland -- we laid this out in our papers -- **he's wrong**. Drugs were added for third-party payors.
> THE COURT: Well, that's what I just said, and he said --
> MR. BERMAN: **Drugs were not added for consumers**. The Exhibit B list was taken from the Fifth Amended Complaint.

April 27, 2009 Tr. at 80:9-19 (Emphasis added).

Even though the undersigned wrote directly to Class Counsel on this issue, as the Court requested,[3] *see* June 21, 2011 Letter to Jennifer Connolly at Exhibit "A" hereto, Class Counsel seek to ignore the issue. They have chosen to not respond (and thus have waived any right to take a position given the Court's direct June 14, 2011 Order). Instead, it is the Defendants who now seek to champion the issue of the expanded scope of the release. And, the Defendants now concede that Certain Named Plaintiffs were correct in their assertions in both their objection Brief and at the April 27, 2009 Fairness Hearing. Defts. Mem. at 1 (describing their memorandum as addressing "the appropriate handling of drugs in the Track 2 settlement that were previously stricken from the litigation").

Defendants' concession at this late juncture undermines their contention that "[n]othing has transpired" since the April 2009 hearing to warrant this Court "chang(ing) its view of the settlement." Defts. Mem. at 1. To the contrary, and despite Class Counsel's prior misrepresentations about the scope of the release in response to the Court's direct inquiry, now the Court is fully aware of the seriousness of the issue and can render a decision as to the propriety of the broad expansion of the proposed release – which contravenes two prior Court Orders, which barred the Newly-Added Drugs from inclusion in the litigation, and,

[3] June 13, 2011 Hrg. Tr. at 65:17-18 (wherein the Court directed the undersigned to "give [Class Counsel] a list of the ones that I struck and that you think shouldn't be in the release.")

importantly, prevented Class Counsel from obtaining any discovery as to the merits of Class claims for such drugs.

II Argument

Track Two Defendants urge that their proposed expansion of the Track Two settlement release to include claims for Newly-Added Drugs is supported by (1) the facts, (2) the law, and (3) the equities. Certain Named Plaintiffs disagree.

A. The Facts Do Not Support Doubling the Scope of the Release at the Eleventh Hour to Include 85 Newly-Added Drugs.

Track Two Defendants ask this Court to "recall the events that led to the April 13, 2006 Order striking certain drugs from the litigation." Defts. Mem. at 2. They then proceed to skew the history of those events in their favor to avoid the unfortunate consequences of such history.

Defendants accurately report that on November 21, 2005, CMO 16 allowed Class Counsel to identify individual class representatives against the Track 2 Two Defendants. *Id*. They conveniently ignore the fact that such "individual class representatives" were the same Certain Named Plaintiffs who now oppose their effort to expand the scope of the case beyond its original borders and force a settlement upon them and the Class without having paid any additional consideration for such claims. Since this court has ruled that Certain Named Plaintiffs withdrew from the case in August 2007, with them should have gone all

the new drugs that they bought, but which were never litigated as part of this case. Instead, as the below history demonstrates, these Newly-Added Drugs have simply been added to the release by Track Two Defendants to get more release for their settlement dollars than they actually bargained for.

1. The Relevant Factual History Shows the Newly-Added Drugs Only Came into the Case By the Purchases of Certain Named Plaintiffs, But Were Stricken By This Court.

To appreciate fully the factual history surrounding the issue of the proper scope the Subject Drugs included in this case, the Court must go back before the 2005-2006 timeframe Track Two Defendants wish the Court to focus upon. This is because the history of this case is one of winnowing – not expanding – the scope of the claims, at the Defendants' continual behest.

On May 13, 2003, this Court issued its Order on the defendants' Motions to Dismiss the original MCC. *See generally, In re Pharmaceutical Industry Average Wholesale Price Litigation* ("*In re AWP*"), 263 F. Supp. 2d 172 (D.Mass. 2003). The Court's dismissal Order was without prejudice to allow Class Counsel thirty (30) days to file "a motion to amend to cure any defects." *Id.* at 195.

On June 12, 2003, Class Counsel filed a Motion to Amend the Complaint, which was granted by the Court on June 18, 2003. That same day, the Amended Master Consolidated Class Action Complaint ("AMCC") was filed. In a process they would later describe as "triage", Class Counsel removed from the MCC and

abandoned seventeen (17) of the twenty-two (22) PAL member associations, leaving only five (5) – four (4) of which are present Court-appointed Track 2 consumer settlement class representatives, *ie.* CANY, NYSSAC, VPIRG, and WCA. *See* Docket No.387. (The fifth Court-appointed Track 2 consumer settlement class representative, HCFA, was dropped as a plaintiff altogether from the AMCC.) The eleven (11) individual consumer plaintiffs listed in the MCC were abandoned in the AMCC, and no new consumer plaintiffs were added.

The AMCC also added, for the first time, two (2) appendices. "Appendix A" purported to identify specific drugs which had inflated AWPs. "Appendix B" purported to detail the specific drugs that were purchased by each individual plaintiff based upon AWP. As there were no consumers listed in the AMCC, no consumer drug purchases were listed in Appendix B.

On November 21, 2003, the Court held a hearing at which it instructed Class Counsel to modify the AMCC. On December 5, 2003, Class Counsel filed a "Notice of Filing of AMCC *Modified Per the Court's Instruction at the November 21, 2003 Hearing* ("Notice"). *See* Docket No. 644. The Notice explained that a "modified" AMCC was being filed that same day to "add( ) allegations regarding the fact that plaintiffs' drug purchases are directly based upon AWP pricing", in direct response to defendants' argument that "under Count 1 plaintiffs have no standing to assert claims because none of the plaintiffs were covered by Medicare

Part B drugs …". *Id*. at 2. Class Counsel also represented that "Appendix B has been amended to reflect purchase of drugs by individual plaintiffs." *Id.* at 3.

On February 24, 2005, a Second Amended Master Consolidated Class Action Complaint ("SAMCC") was filed. *See* Docket No.1377. The SAMCC also included the same Appendices as the AMCC, updated to reflect the individual purchases of certain newly-added plaintiffs (which were later dropped by Class Counsel without explanation).

On February 24, 2004, the Court ruled on defendants' motions to dismiss the SAMCC. *In re AWP*, 307 F.Supp.2d 196 (D.Mass. 2004).

On October 17, 2005, a Third Amended Consolidated Class Action Complaint ("TAMCC") was filed in order to comply with the Court's class certification order.[40] *See* Docket No.1781-1787. The TAMCC added Certain Named Plaintiffs as proposed representatives for Track Two, and also included updated Appendices reflecting the individual purchases of Certain Named Plaintiffs.

Approximately six months later on March 1, 2006, a Fourth Amended Master Consolidated Class Action Complaint ("FAMCC") was filed. *See* Docket No.2171-2176.

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[40] *See In re AWP*, 230 F.R.D. 61, 66 (D.Mass 2005)(allowing "plaintiffs [to] amend the SAMCC to propose individual class plaintiffs who are Medicare Part B beneficiaries")

Also on March 1, 2006, Class Counsel filed a "Proposed Consolidated Order Re: Motion for Class Certification Track 2", Versions 1 and 2. *See* Docket Nos. 2169 and 2170 respectively. Class Counsel proposed that this Court certify the following Certain Named Plaintiffs as class representatives for Track 2, Class 1 for the listed defendant Sub-Classes:

- Harold Carter, as class representative against defendant Abbott, Fujisawa, Amgen;
- Roger Clark, as class representative against defendant Baxter, Abbott, Bayer, Sicor, Amgen and Pfizer;
- Susan Ruth Aaronson, as class representative against defendant Aventis, Baxter, Dey, Pfizer, Abbott, Sicor, Fujisawa, Watson;
- Joyce Howe, individually and on behalf of the Estate of Robert Howe, as class representative against Baxter, Fujisawa, Sicor, Watson, Aventis, Abbott, Immunex, Amgen;
- Larry Young, individually and on behalf of the Estate of Patricia Young, as class representative against defendants Aventis, Fujisawa, Pfizer, Pharmacia, Abbott, Bayer, Watson, Baxter, Sicor, Amgen;
- James Monk, as class representative against defendant Aventis;
- Virginia Newell, as class representative against defendants Amgen and Aventis;
- Oral Roots, as class representative against defendants Pfizer and Dey; and
- Hunter Walters, as class representative against defendant Dey.

On March 14, 2006 – which is where Track Two Defendants pick up the relevant history in their Brief – Defendants filed Track Two Defendants' Motion to Strike Portions of the Fourth Amended Master Consolidated Complaint ("FAMCC") and Notice of Errata, alleging, *inter alia*, that the plaintiffs were attempting to covertly expand the number of drugs for Track 2 defendants. *See* Docket No. 2249. On April 10, 2006, this Court electronically entered its order **striking the added new drugs**. ("I strike the new drugs").

Approximately two months later, on May 8, 2006, Class Counsel filed Plaintiff's Motion to Certify Claims with Respect to Track Two Defendants.[47]

On April 26, 2007, Co-Lead Counsel filed Class Plaintiffs' Motion for Leave to File an Amended Complaint as well as a proposed Fifth Amended Master Consolidated Class Action Complaint. *See* Docket Nos. 4105 and 4106.

On May 10, 2007, Defendants filed Track Two Defendants' opposition to Class Plaintiffs' Motion for Leave to File an Amended Complaint. As Defendants

[47] Class Counsel chose to not propose Certain Named Plaintiffs Virginia Newell, James Monk, Oral Ray Roots or George Baker Thomson as Track Two class representatives **because they purchased purportedly "new drugs" which this Court ordered stricken from the FAMCC on defendants' motion**. Nevertheless, and without explanation by the settling parties, these drugs have been slipped back into the list of drugs included in the Track 2 settlement. Certain Named Plaintiffs object to this reversal of position, and the inclusion of drugs like Aventis' Eligard (paid for by Mr. Monk), and Pharmacia's Trelstar (paid for by Mr. Thomson) and Depo-Provera (paid for by Mr. Roots) in the Track 2 settlement, because such inclusion violates this Court's prior "no new drugs" orders and deprives these plaintiffs of a full and fair adjudication and settlement of their claims for these drugs.

pointed out, the proposed Fifth Amended Complaint "added dozens drugs previously excluded from this case …". Track Two Defendants expressly asked this Court to reject "Plaintiffs' attempt to add drugs previously excluded by the Court's April 10, 2006 "no new drugs" order …". *See* Docket No. 4181.

On September 10, 2007 this Court agreed with Defendants. It issued its Order re: Motion for Leave to File and Amended Complaint (Docket No. 4105), **denying the Motion to Amend "to the extent the Amendment adds new drugs.".** *See* Docket No. 4702 at 6.

On February 17, 2009, a Revised Fifth Amended Master Consolidated Class Action Complaint ("RFAMCC") was filed. *See* Docket No. 5902. Class Counsel filed a Motion to Amend the Complaint on April 26, 2007, which included a Proposed Fifth Amended Master Consolidated Complaint. *See* Docket at No. 4105. When that Motion was granted, Class Counsel filed the RFAMCC. This pleading supplanted the prior FAMCC – which Track Two Defendants erroneously rely upon in support of their claims about the propriety of the present scope of the release. In the RFAMCC, Class Counsel try to slip back into the case all the Newly-Added Drugs that were stricken by the Court, not once [as Track Two Defendants suggest], but twice. *See* Docket No.5919.

As the above recounted history shows, the April 13, 2006 Order striking the Newly-Added Drugs was far from a "routine case management decision", as Track

Two Defendants now claim. Defts Mem. at 3. It was a ruling on the merits as to Class Counsel's Motion for Leave to Amend the complaint, which Track Two Defendants opposed. Regardless of whether the Newly-Added Drugs were "identified by Class Counsel as 'AWP Inflated Drugs'", *id*., it is clear on this record that the Court's Order ***barred*** Class Counsel from proceeding on claims for these drugs. It was more than a "setback"; it was a judicial bar. As such, it had the legal effect of excluding the claims for these separate and distinct drugs from this litigation – for litigation or settlement purposes. To suggest that "the door remained open to future claims" in this Court on any of the Newly-Added Drugs makes a mockery of this Court's rulings in this massive MDL, which has systematically winnowed and honed plaintiffs' claims to only a justiciable core.

If this were unclear in the wake of the Court's April 13, 2006 Order, it was underscored by the Court's subsequent September 10, 2007 Order – which Defendants conveniently ignore in their Brief. That Order rebuffed for the second time Class Counsel's effort to slip into the case via complaint amendment a host of Newly-Added Drugs. As set forth below, beyond the fact of their exclusion, the law of this case compels their exclusion at the most important time – settlement – when the Court must confront issues of the merits of the claims and their relative value. Without any of the Newly-Added Drugs ever having been included in this case – save in the minds of Class Counsel who tried repeatedly to put them into

their complaints – there was never any discovery to inform the merits of the Certain Named Plaintiffs' claims for such drugs. In the absence of such discovery, the settling parties have nothing to point to as evidence that the merits were properly considered in their respective decisions to settle.

2. The Release Should Be Limited to Subject Drugs Only.

As listed in the Track Two Defendants' chart filed of record during the Track 2 class certification proceedings (Dkt. No. 3500), only the following drugs are properly included in the Track 2 Settlement Release:

#	Drug Name	Manufacturer
1	Acetylcysteine	Abbott
2	Acyclovir sodium	Abbott
3	A-methapred	Abbott
4	Amikacin sulfate	Abbott
5	Calcijex	Abbott
6	Cimetidine hydrochloride	Abbott
7	Dextrose	Abbott
8	Diazepam	Abbott
9	Fentanyl citrate	Abbott
10	Furosemide	Abbott
11	Gentamicin sulfate	Abbott
12	Heparin	Abbott
13	Leucovorin calcium	Abbott
14	Lorazepam	Abbott
15	Sodium Chloride	Abbott
16	Tobramycin sulfate/Tobramycin sodium chloride	Abbott
17	Vacomycin	Abbott

18	Aranesp	Amgen
19	Epogen	Amgen
20	Kineret	Amgen
21	Neulasta	Amgen
22	Neupogen	Amgen
23	Anzemet	Aventis
24	Calcimar	Aventis
25	Intal	Aventis
26	Taxotere	Aventis
27	Aggrastat	Baxter
28	Ativan	Baxter
29	Bebulin	Baxter
30	Brevibloc	Baxter
31	Buminate	Baxter
32	Cisplatin	Baxter
33	Claforen	Baxter
34	Dextrose	Baxter
35	Gammagard	Baxter
36	Gentamicin Sulfate	Baxter
37	Heparin	Baxter
38	Iveegam	Baxter
39	Osmitrol	Baxter
40	Recombinate	Baxter
41	Sodium Chloride	Baxter
42	Travasol	Baxter
43	Vancocin	Baxter
44	Cipro IV	Bayer
45	DTIC Dome	Bayer
46	Gamimune	Bayer
47	Koate	Bayer
48	Kogenate	Bayer
49	Mithracin	Bayer
50	Acetylcysteine	Dey
51	Albuterol Sulfate	Dey
52	Cromolyn Sodium	Dey

53	Ipratropium	Dey
54	Metaproterenol Nebulizer	Dey
55	Aristocort	Fujisawa
56	Aristospan	Fujisawa
57	Cefizox	Fujisawa
58	Lyphocin	Fujisawa
59	Nebupent	Fujisawa
60	Prograf	Fujisawa
61	Vinblastine sulfate	Fujisawa
62	Acyclovir Sodium	Fujisawa
63	Dexamethasone Sodium	Fujisawa
64	Doxorubicin Hydrochloride	Fujisawa
65	Flourouracil	Fujisawa
66	Gentamicin Sulfate	Fujisawa
67	Leucovor CA	Immunex
68	Leukine	Immunex
69	Methotrexate Sodium	Immunex
70	Novantrone	Immunex
71	Thioplex (Thiotepa)	Immunex
72	Adriamycin	Pharmacia
73	Adrucil	Pharmacia
74	Amphocin	Pharmacia
75	Bleomycin Sulfate	Pharmacia
76	Cytarabine	Pharmacia
77	Depo-Testosterone	Pharmacia
78	Etoposide	Pharmacia
79	Neosar	Pharmacia
80	Solu-Cortef	Pharmacia
81	Solu-Medol	Pharmacia
82	Acyclovir Sodium	Sicor
83	Amikacin Sulfate	Sicor
84	Doxorubicin HCL	Sicor

85	Etoposide	Sicor
86	Leucovorin Calcium	Sicor
87	Pentamidine Isethionate	Sicor
88	Tobramycin Sulfate	Sicor
89	Amikacin Sulfate	Gensia
90	Amphotericin B	Gensia
91	Etoposide	Gensia
92	Leucovorin Calcium	Gensia
93	Dexamethasone Acetate	Watson
94	Dexamethasone Sodium	Watson
95	Diazapam	Watson
96	Gentamycin	Watson
97	Vancomycin	Watson
98	Ferrlecit	Watson
99	Infed	Watson

The following Newly-Added Drugs are improperly included in the Track 2 Release pursuant to the Court's multiple rulings barring the addition of new drugs:[4]

#	**Drug Name**
1	Accuneb
2	Adenoside
3	Alcohol Injection
4	Aminacaproic acid
5	Aminosyn/Aminosyn II / Amino acid
6	Aromasin
7	Azmacort
8	Bioclate
9	Bupivacaine

[4] Class Counsel failed to list the corresponding drug manufacturers for any of the drugs included in the Track 2 release. For the Court's convenience, the manufacturers are identified in the above chart.

10	Camptosar/Irinotecan hydrochloride
11	Carbocaine/Mepivicaine
12	Chromium tr meta / Chromic chloride
13	Ciprofloxacin hydrochloride
14	Cleocin T/Clindamycin phosphate
15	Copper Trace / Cupric Chloride
16	Cytosar-U
17	Depo provera / Medroxyprogesterone Acetate
18	Testosterone cypionate
19	Dexamethasone sodium phosphate
20	Dextrose sodium chloride / Ringers lactated with dextrose
21	Dicarbazine
22	Diltiazem hydrochloride
23	Dopamine hydrochloride
24	Eligard
25	Ellence / Epirubicin HCL
26	Enalaprilat
27	Enbrel
28	Epinephrine
29	Erythromycin/Erythomycin base
30	Estradiol
31	Famotidine
32	Fluphenazine HCL
33	Gammagard S/D / Gammar / Gammar P.I.V.
34	Gentran / Gentran NACL
35	Glycopyrrolate
36	Helixate / Helixate FS
37	Heparin lock flush / Heparin Sodium
38	Humate - P
39	Hydromorphine
40	Idamycinc / Idarubicin hydrochloride
41	Imipramine HCL
42	Ketoralc / Ketoralac tromethamine
43	Labetalol
44	Lasix
45	Levofloxacin

46	Lidocaine hydrochloride
47	Liposyn II / Fat emulsion
48	Lovenox
49	Magnese chloride
50	Magnesium chloride
51	Magnesium sulfate
52	Mannitol
53	Marcaine
54	Medrol / Methylprednisone
55	Metoclopramide
56	Midazolam hydrochloride
57	Monoclate / Monoclate-P
58	Mononine
59	Morphine Sulfate
60	Nadolol
61	Nalbuphione
62	Cyclophospamide
63	Neostigmine methylsulfate
64	Novacaine/Procaine
65	Pancuronium bromide
66	Pentam
67	Perphenazine
68	Phenylephrine
69	Potassium acetate / Potassium chloride
70	Promethazine
71	Propranolol HCL
72	Propofol
73	Ranitidine HCL
74	Sodium acetate
75	Hydrocortisone sodium succinate
76	Succinylcholine chloride
77	Toposar
78	Travasol with Dextrose
79	Trelstar/Triptorelin pamoate
80	Vancocin HCL / Vancomycin HCL
81	Verapamil HCL
82	Vincristine / Vincristine sulfate
83	Water for injection bacteriostatic
84	Zemplar

85	Zinc chloride

3. Track Two Defendants Should Be Judicially Estopped from Making Any Claim as to their Unwillingness to Settle Without the Newly-Added Drugs.

Defendants make the *ipse dixit* statement that "the truth is that the Track Two Defendants would not have entered into the settlement – or would certainly have paid much less than $125 million -- if drugs identified during the litigation were excluded from the settlement." Defts. Mem. at 4-5. This is a statement they cannot make, and cannot support, given the manner in which they chose to settle this case. As such, it must be excluded from the Court's consideration of the request to expand the scope of the release.[5]

As the Court well knows, the Track Two Defendants insisted on a "blind" settlement whereby the Class and the Court were "blind" as to the reasons why each individual Defendant was settling and the relative amounts they were paying. Accordingly, there is no evidence of record that the Newly-Added Drugs were considered by either Class Counsel (or Class Counsel's expert) in negotiating the

[5] If the Court chooses to consider the proffer that the Track Two Defendants would not have settled without the inclusion of the Newly-Added Drugs, then their respective shares in the "blind settlement" should be made public so Certain Named Plaintiffs and the Class can assess the actual dollars they are paying for the claims now being released. Defendants cannot have it both ways: concealing their proportionate shares, but then boldly claiming they would not have paid $125 million if the drug list were limited to only those drugs in the underlying litigation.

$125 million settlement with the Track Two Defendants. Indeed, the record evidence shows otherwise.

At the April 27, 2009 Fairness Hearing, Class Counsel explained the focus of their settlement posture as follows:

> MR. BERMAN: So I thought I'd start off by talking about the reasonableness of the settlement amount of $125 million. Prior to the trial -- and I'm talking about the trial we had of the Massachusetts class -- **we had Dr. Hartman do a damage study for all the defendants, and his number came out at $1.2 billion.** It seems like a large number, but the trial altered the landscape. So if you look at the defendants in the Track Two settlement, we have Amgen –
> THE COURT: Is that all the defendants in Track Two or all the defendants in Track One and Track Two?
> MR. BERMAN: Track Two only. **And if you break those defendants down into the brand-name drug defendants and the multi-source defendants, Dr. Hartman estimated $316 million in damages from Amgen, Aventis, and Watson, and then roughly $800 million from the remaining defendants. All are multi-source drugs.** So we had the trial, and we learned the road map from the trial. **One of the important points in evaluating liability was evidence of spread marketing**, and you recall the do-the-math type of documents that we spent a lot of time on at the trial. With respect to the multi-source defendants, there were no such documents. We had very little evidence that the multi-source defendants were busy marketing the spread. So we had a liability hole, a significant liability hole.

April 27, 2009 Tr. at 8:13- 9: 14 (Emphasis added). Dr. Harman's "damage study" was for the Subject Drugs in the case at the time; it did not included any of the Newly-Added Drugs.

This fact was confirmed by Class Counsel at the most recent Fairness Hearing:

> You know, at the settlement negotiations, we sat down with each defendant and presented them with the evidence we had, and in some cases it was a single sheet of paper. Of all the millions of documents, we had one or two documents that may have shown spread marketing. So we had a very weak spread marketing case….

June 13, 2011 Tr. 8:18-23.

No one has suggested that the Newly-Added Drugs were part of the settlement calculus; nor could they. And since the value of the claims for these 85 drugs was never included in the negotiations, the inclusion of Newly-Added Drugs only takes away dollars that would inure to the proportionate benefit of the Class.

B. The Law Does Not Support Expansion of the Scope of a Class Release to Include Drugs that Were Previously Barred from the Case and for which Class Counsel Obtained No Discovery As to the Merits of Such Claims By Which To Evaluate Settlement.

Track Two Defendants claim that "it is hornbook law" that "broad class action settlements are common." Defts. Mem. at 3. The broad principle notwithstanding, Defendants fail to demonstrate how the proposed release in this case is legally permissible given the law of this case and the realities of the litigation, caused by their affirmative steps to limit the scope of the claims against them. Here, there are three legal reasons why their proposed expanded release – nearly doubling the size of the list of Subject Drugs – should not be permitted.

1. Track Two Defendants Are Estopped from Taking Inconsistent Legal Positions in this Case.

"As a general matter, the doctrine of judicial estoppel prevents a litigant from pressing a claim that is inconsistent with a position taken by that litigant

either in a prior legal proceeding or in an earlier phase of the same legal proceeding." *See Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 32-33 (1st Cir.2004)(*quoting InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir.2003)); *see also, Cadle Co. v. Schlichtmann, Conway, Crowley & Hugo*, 338 F.3d 19, 22 (1st Cir. 2003)(same). Here, Track Two Defendants should be stopped from arguing – in support of their settlement release – that the claims of the Newly-Added Drugs had some value such that they would not have settled without their inclusion. Such an argument is completely contrary to their prior arguments in the earlier phase of this same litigation that these claims should be excluded, not only from the litigation but from all discovery.

2. The Law of this Case, Brought About by Affirmative Rulings Obtained by the Track Two Defendants, Prevents the Claims from Being Expanded.

"The law of the case doctrine 'posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.' " *Remexcel Managerial Consultants, Inc. v. Arlequin*, 583 F.3d 45, 53 (1st Cir .2009) (quoting *Arizona v. California*, 460 U.S. 605, 618, 103 S.Ct. 1382, 75 L.Ed.2d 318 (1983)). As the Court in *Remexcel* held, "[t]he doctrine has two branches. … The second branch … 'contemplates that a legal decision made at one stage of a criminal or civil proceeding should remain the law of that case throughout the litigation, unless and until the decision is modified or overruled by a higher court." We have described the many 'salutary policies' that

underlie the law of the case doctrine, including: 'afford[ing] litigants a high degree of certainty as to what claims are-and are not-still open for adjudication'; 'further[ing] the abiding interest shared by both litigants and the public in finality and repose'; 'promot[ing] efficiency'; and 'increas[ing] confidence in the adjudicatory process.'" *Id*. (citations omitted).

Here, the Track Two Defendants helped to create the law of the case that precluded the Newly-Added Drugs from consideration in this case, including and especially the discovery phase that, in hindsight, might have assisted Defendants at this stage. However, as the First Circuit admonished in such a situation, [i]f defendants feel victimized by this outcome, they have only themselves to blame. Their stubborn refusal to participate in discovery precluded the possibility of any factual development that might have helped their case. *Id*. at 54-55.

3. The Cases Cited By Track Two Defendants Are Inapposite.

"'Basic to [the process of deciding whether a proposed settlement is fair and equitable] in every instance, of course, is the need to compare the terms of the compromise with the likely rewards of litigation.' In so doing, a court must 'apprise [itself] of all facts necessary for an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated'" *Acosta v. Trans Union, LLC,* 243 F.R.D. 377, 389 (C.D.Cal.,2007) (internal citations omitted).

In this case, there is no dispute that there was no discovery as to the merits of the claims for the Newly-Added Drugs. Indeed, as set forth above, that is one of the primary reasons why Track Two Defendants fought Class Counsel's efforts to expand the scope of the Subject Drugs in the complaint: to avoid discovery. In the absence of any discovery regarding the Newly-Added Drugs, it is impossible for the Court to estimate the range of possible outcomes or to ascribe any probability to each point on the range of possible outcomes, as required. *See, e.g., Reynolds v. Beneficial Nat'l Bank*, 288 F.3d 277, 285 (7th Cir. 2002) (reversing settlement approval because "the judge made no effort to translate his intuitions about the strength of the plaintiffs' case, the range of possible damages, and the likely duration of the litigation if it was not settled now into numbers that would permit a reasonable evaluation of the reasonableness of the settlement.")

This point is underscored by the fact that Class Counsel arrived at the $125 million settlement based on their drug-by-drug analysis of the potential liability and damages of the Track 2 Defendants' Subject Drugs. *See* June 13, 2011 Hrg. Tr. at 7:2-7 (wherein Class Counsel attempted to justify the fact that the percentage of damages recovered against the Track 2 Defendants is smaller compared to that of AstraZeneca and BMS with respect to Class A drugs because "[Class Counsel] had to evaluate the liability case, and we just didn't have the hot documents, you know, showing pushing the spread to physicians like we did with AstraZeneca or

with BMS. So the liability case wasn't nearly as strong...."); *Id.* at 8:16-24 (wherein Class Counsel attempted to justify the low settlement amount for Class B drugs based in part on Class Counsel's belief that "there was just no evidence of spread marketing [ ] Of all the millions of documents, we had one or two documents that may have shown spread marketing. So we had a very weak spread marketing case, and for all those reasons, we wound up with a $25 million settlement."); *Id.* at 20:10-12 (arguing that Class A damages should be doubled and not tripled during the heartland period because of Class Counsel's belief that "the evidence is not as strong as it was in the AstraZeneca case.")

This absence of discovery of the merits of the claims sought to be settled prevents this Court from assessing the fairness of the proposed settlement of anyof the Newly-Added Drugs. This problem is perhaps best demonstrated by considering two Newly-Added Drugs: Sanofi-Aventis' branded drug Eligard, and the Pharmacia's branded drug Trelstar. Both drugs are "LHRH-agonists used treat prostate cancer in men; they are the same as TAP Pharmaceutical's drug Lupron (which nationwide claims were resolved in MDL-1430 for $150 million -- $25 million more than the entire proposed Track 2 Settlement) and AstraZeneca's Zoladex (which nationwide claims were resolved in this Court for $24 million for

Class 1 consumers,[6] and $103 million for Classes 2 and 3, a settlement fund that exceeds the total Track Two settlement even without including the additional consideration noted at footnote 6.) While the liability evidence concerning these drugs is equally strong as it was for Lupron and Zoladex – and by Class Counsel's assessment would warrant comparable settlements -- Class Counsel have no discovery by which to make such assessment. They simply agreed after the fact to include these drugs in the release – because the Track Two Defendants asked them to do so.

The same is true as to the 83 other Newly-Added Drugs improperly lumped into the group of "Class B drugs" due to the fact that they are cancer agents for which the evidence is strongest. This Court has required such drugs to be compensated at the highest levels in settlement, especially in the "Heartland period".

The precedents cited by Track Two Defendants in support of their late-inclusion of the Newly-Added Drugs in the settlement release permit such expansion of the Class claims at the time of settlement only in the limited circumstance where "the released conduct arises out of the 'identical factual predicate' as the settled conduct." Defts. Mem. at 3 (*quoting Wal-Mart Stores, Inc.*

[6] The $24 million settlement fund for Class 1 consumers does not include the additional $8.6 million AstraZeneca paid for attorneys fees and costs as part of the Class 1 settlement, nor does it include the Notice costs which were also paid in addition to the $24 million settlement fund. Here, Class Counsel's fees and costs, as well as the Notice costs are being taken off the top of the settlement fund decreasing the net amount available to the Classes.

v. Visa USA, Inc., 396 F.3d 96, 107 (2d Cir, 2005). In these cases, unlike here, the court permitted broad discovery into the claims alleged. It was such discovery that permitted class counsel to inform themselves as to the "identical" nature of the additional claims being settled, and their relative merits, so as to properly assess their settlement value. Here, such discovery is completely lacking.

Defendants place great emphasis on this Court's prior decision, affirmed on appeal, in *City P'ship Co. v. Atlantic Acquisition Ltd. P'ship*, 100 F.3d 1041 (1st Cir. 1996). There are several distinguishing features of that case that make it wholly inapposite to this case.

First, the First Circuit noted that "Intervenors participated in the settlement negotiations and had access to all the discovery." *Id*. at 1043. This was critical to the Court because it was by the Intervenors' participation the Court was able to find the potential conflict of interest eliminated. Id. at 1045 ("The Intervenors' participation eliminated the risk that a conflict problem would skew the presentation of the valuation issues…") Here, as the Court well knows, Certain Named Plaintiffs, and their counsel, were deliberately excluded from any role in the settlement, its allocation, or even its recent "re-allocation." The same conflict of interest exists in this case as between the value of the Class claims for Subject Drugs – which the litigation was focused upon – and the value of the non-Class members' claims for Newly-Added Drugs, which were only swept into the case by

operation of the settlement release. There has been no showing that the interests of consumers of Newly-Added Drugs were adequately represented at the settlement or allocation bargaining tables. Indeed, the already-conflicted PAL representative, Mr. Sugarman-Brozan, and the HCFA lawyer appear to have been involved on all consumer settlement issues.

Second, the Court in *City Partnership* gave the settling parties the benefit of a presumption in favor of the settlement because "sufficient discovery" had been conducted as to all the settled claims. *Id*. at 1043. Indeed, the First Circuit affirmed this Court by "considering the evidence" concerning the relative value of the newly-added claims. *Id*. at 1046. Here, because this Court twice denied Motions for Leave to Amend the complaint to add the Newly-Added Drugs, no discovery was produced by any Track Two Defendant. The record before this Court is thus completely lacking on the settlement value of the claims for Newly-Added Drugs. Therefore, there can be no presumption in favor of the settlement of the claims for Newly-Added Drugs, as the settling parties have argued generally in their moving papers.

Third, the claims concerning Newly-Added Drugs do not present claims that were either "alleged in the complaint" – because they were stricken by court Order twice – or that "could have been asserted in the litigation" by reason of their alleged "identical factual predicate" to the claims at issue. Defts. Mem. at 3. To

hold otherwise would allow settling defendants to include their entire product lines at the time of settlement, without regard to the relatedness of such product to the "factual predicate" of the products at issue. Nothing would prevent the Track Two Defendants from including all their prescription drugs, not just those alleged by the plaintiffs at one time to have been at issue. Unlike in City Partnership, where this Court had the benefit of discovery and the vigorous participation of Intervenor counsel to guide its decision about the fairness of the settlement release, here we have only opportunistic settling defendants and pacifist Class Counsel, neither of which warrant the expansion of the scope of the release.

C. The "Equities", If Relevant, Do Not "Argue Strongly In Favor" of the Expanded Release In This Case.

After paying lip service to the importance of the "equities" in this Court's decision whether to allow the settlement release to encompass all the Newly-Added Drugs, Track Two Defendants cite no law in support of their claim that equity has any bearing on the issue. Instead, they allege only that "carving these drugs out of the Track 2 Settlement … would make no sense, would only serve to delay the settlement, and would deprive thousands of consumers … of settlement benefits agreed to by all parties more than three years ago after long hard negotiations." Defts. Mem. at 5.

What "makes no sense" for the Class of consumers on whose behalf this case was ostensibly litigated for over ten (10) years is to invite thousands of non-

Class members now to share in (and dilute) the already scarce settlement proceeds without any additional consideration having been paid. As for delay, no explanation has been given by either Class Counsel or Track Two Defendants as to why ***they waited*** more than three years to present this settlement for final approval. (The record in this court is clear that the delays were occasioned by the settling parties, and no one else.) And, to "deprive thousands of consumers" of "settlement benefits" that do not belong to them and which reduce the settlement benefits that properly belong to others, is not deprivation, but justice. Those consumers who purchased Newly-Added Drugs give nothing up when this Court restores the release to its proper scope. They are free to pursue these meritorious claims – denied by this Court -- on their own, or on behalf of putative classes, in whatever forum they so choose. *See Smith v. Bayer Corp.*, 131 S.Ct. 2368 (2011).

Dated: July 5, 2011

_____/s/_____

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CERTIFICATE OF SERVICE

I, Donald E. Haviland, Jr., hereby certify that on July 5, 2011 the foregoing Response to Track 2 Defendants' Memorandum in Support of Track Two Class Action Settlement was filed via CM/ECF and all counsel of record were served via ECF notification.

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr.